THE LEAPFROG GROUP
Giant Leaps for Patient Safety

The Leapfrog Consolidated Appropriations Act Compliance Webinar Series

Session 3: Five Key Actions for CAA Pharmacy Benefit Compliance

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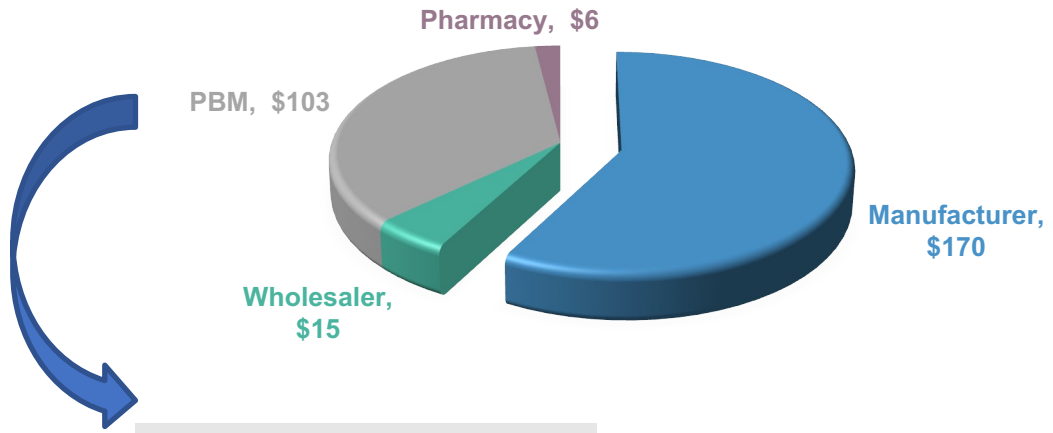
Four areas to assess readiness with the Consolidated Appropriations Act (CAA) healthcare spending/pharmacy reporting requirements

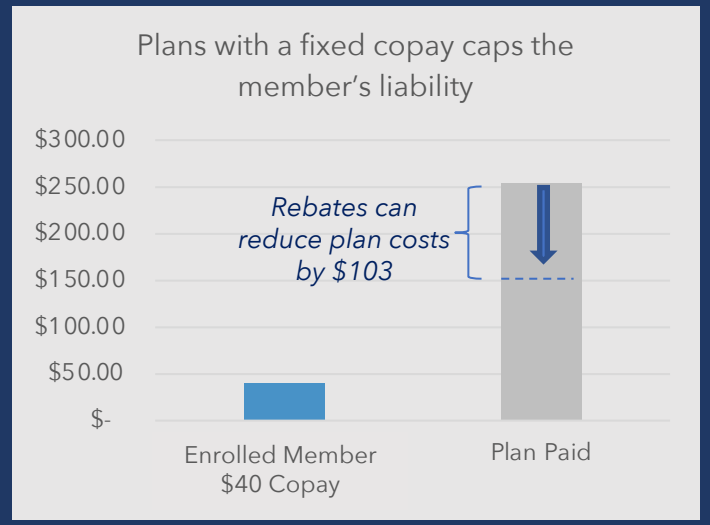
Dollars Exchanged in Current State

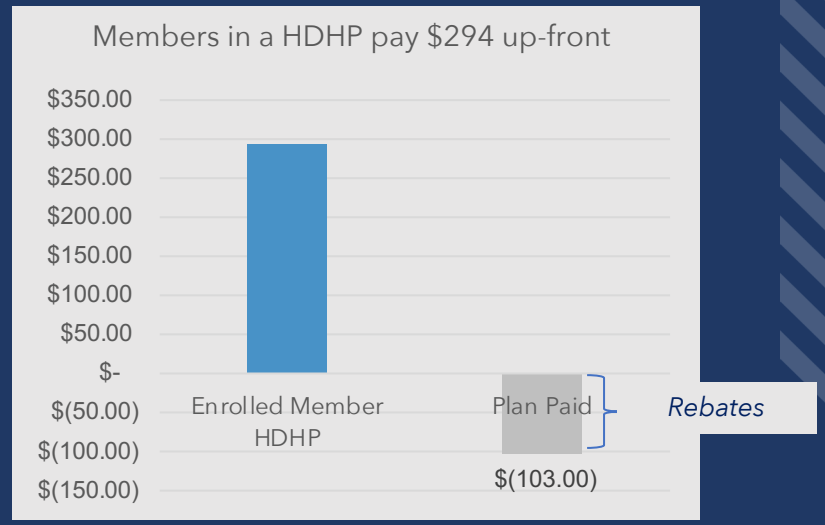
Out-of-Pocket for a Retail Brand Drug after Discount is $294



Plan Sponsor (Employer) receive 0% - 100% of PBM collected rebates and fees based on the PBM contract

Brand Rx Out-of-Pocket Spend is $191-$294 based on share of rebate/fees





Adapted from: https://www.drugchannels.net/2017/08/follow-dollar-math-how-much-do.html

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Agenda

What is a gag clause and do you have them in your service agreements?

Do you have the data required in order to meet statute requirements?

Does your TPA/PBM service agreements include definitions that align with the statute?

Do you have a formal healthcare fiduciary process?

Group Health Provisions of the Consolidated Appropriations Act

Why Was the Legislation Created?

- Lack of clarity in the role of Plan Sponsor as the Fiduciary under ERISA/PHSA and specific responsibilities
- Contracts that restrict Plan Sponsors from full access to their data
- Lack of transparency in pricing and benefit plan administration
- Accountability for services provided
- Need for more aggressive enforcement of the federal Mental Health Parity and Addiction Equity Act of 2008

*The legislation was signed into law December 27, 2020 and established the **Plan Sponsor as the Fiduciary** under ERISA/PHSA/IRS tax code.*

Employer Fiduciary responsibilities across 4 key areas:

- Removes gag clauses from service provider contracts on price and quality information
- Establishes reporting requirements (i.e. Rx)
- Requires the disclosure of direct and indirect compensation from all service providers
- Requires parity in substance abuse and mental health benefits

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Prohibition of Gag Clauses

Plan Sponsor agreements with service providers must provide access to provider-specific cost or quality information for the Fiduciary to:

- Show that employee costs related to claims are expended in an efficient manner
- Provide enrollees with access to information to make informed, cost-effective healthcare decisions
- Share information with the Plan Sponsor to identify waste through comparative analytics

Plan Sponsors must be able to use their data to verify prudent spending of plan assets in order to meet Fiduciary Responsibilities.

They must annually attest to the Secretaries of DOL, HHS and Treasury that the plan complies with the prohibition of gag clauses.

ACTION ITEM

✓ **Closely review** Third Party Administrators and other Provider agreements for gag clauses, which must be removed.

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Reporting on Healthcare Spending

The CAA requires Plan Sponsors to report certain information to HHS, DOL, and Treasury, including:

Total spending on health care services by such group health plan or health insurance coverage, broken down by the type of costs for the following.

1. Hospital costs
2. Health care provider and clinical service costs, for primary care and specialty care separately
3. **Costs for prescription drugs**
4. Other medical costs, including wellness services

Plan Sponsors may need an increased level of data from TPAs and Insurance Carriers to meet data access for enrollees and annual reporting requirements.

ACTION ITEM

✓ **Agreements with TPAs** will need to be revised to allow full access to claim information, with financial information, provider information, and service codes.

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Prescription Drug Disclosures

The CAA requires Plan Sponsors to report certain information to HHS, DOL, and Treasury, including:

1. The beginning and end dates of the plan year
2. The number of plan participants and beneficiaries
3. Each state in which the plan is offered
4. The 50 brand prescription drugs most frequently dispensed (including number of paid claims for those drugs)
5. The 50 most costly prescription drugs by annual spend (including the annual spend amount for those drugs)
6. The 50 prescription drugs with the greatest increase in plan expenditures
7. Information about the total spending on health care services
8. The average monthly premium paid by employers and employees
9. The impact on premiums of rebates, coupons, other similar remuneration paid by drug manufacturers to the plan
10. Any reduction in premiums and out-of-pocket costs associated with rebates, fees or other remuneration described in #9

Plan Sponsors will need an increased level of data from PBM's to meet reporting criteria. Currently, this information is not available.

Annual reporting requirements demonstrate that the Plan Sponsors actions serve the economic interest of the enrollee.

ACTION ITEM

✓ **Agreements with TPAs and PBMs** will need to be revised to allow full access to claim information, rebates, fees, and other forms of remuneration.

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Drug Rebates/Remuneration Definition

Employers required to understand and declare all remunerations are reasonable

Federal Definitions:

1. All remuneration received with respect to prescription drugs prescribed to enrollees
2. Sources of remuneration include pharma manufacturers, retail pharmacies and vendors
3. Remuneration examples include chargebacks, rebates, cash discounts, free goods contingent on purchase, coupons, grants, and price concessions.
4. Remuneration includes bona fide service fees for services performed on behalf of pharma manufacturer by the TPA or PBM

ACTION ITEM

- ✓ **Ensure all fees including the cost of the drug equal 100% of the expense.**
- ✓ **Obtain a categorized level of detail of all expenses paid for prescription drugs**
- ✓ **Document why fees are paid to the PBM**
- ✓ **Document the plans analysis to declare these fees are reasonable and appropriate**

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Rebate (Any Remuneration) Reporting

Plan sponsors must report how rebates, fees, and any other remuneration paid by drug manufacturers reduce premiums and out-of-pocket costs for enrollees.

Reporting includes payments made to the:

- Plan
- Coverage
- **Administrators**
- **Service providers, with**

Report specifications include:

- Amounts paid for each therapeutic class of drugs; and
- Amounts paid for each of the 25 drugs that yielded the highest amount of rebates and other remuneration from drug manufacturers

ACTION ITEM

- ✓ **Require disclosure from TPAs and PBMS** of the rebates, fees, and other forms of remuneration not passed to the plan.
- ✓ **Obtain an attestation from TPAs and PBMs if the plan is 100% pass through** of the rebates, fees, and other forms of remuneration were not retained by the service provider

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Reporting due 12/27/2022

Delegating reporting requirements does not relieve the Employer plan from knowing the details of their expenses are reasonable

"Departments strongly encourage plans and insurers to start working to ensure that they are in a position to be able to report the required information [by statute deadlines]"

https://www.federalregister.gov/documents/2021/11/23/2021-25183/prescription-drug-and-health-care-spending

Plan Sponsors will need to ensure they are in a position to meet the reporting requirements.

Annual reporting requirements demonstrate that the Plan Sponsors actions serve the economic interest of the enrollee.

ACTION ITEM

✓ **Understand how the report is specific for your plan and how this report is used bu the plan to fulfill premium reporting requirements.**

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Summary

Where do you begin?

1. Evaluate your current healthcare procurement process to identify the lack of disclosure and transparency.
2. Based on #1 – are the discovered fees and contract language in the best interest of the plan and your participants.
3. Talk to an informed consultant and be engaged with an ERISA attorney

Consolidated Appropriations Act Questions for Employers to Ask their Third Party Administrators

Areas covered in each question

Agreed to definitions

Confirmed in contract language

Agreed to indicators/classifications

Necessary data provided to verify and audit

Required out of Fiduciary responsibilities out of federal law, CAA

Specific Federal reporting requirements in the CAA

Question and Topic	Required in the Consolidated Appropriations Act (CAA)
Wasteful Drug	Section 201, beginning on page 1709. Increasing transparency by removing gag clauses on price and quality information.
Discounts	Section 201, beginning on page 1709. Increasing transparency by removing gag clauses on price and quality information.
Rebates	Section 2799A-10, beginning on page 1737. Reporting on pharmacy benefits and drug costs.
Specialty	Section 201, beginning on page 1709. Increasing transparency by removing gag clauses on price and quality information.
Prescription Drug Disclosures	Section 2799A-10, beginning on page 1737. Reporting on pharmacy benefits and drug costs.
Prohibition on Gag Clauses	Section 201, beginning on page 1709. Increasing transparency by removing gag clauses on price and quality information.
Compensation Disclosures	Section 202, beginning on page 1713. Disclosure of direct and indirect compensation
Mental Health & Substance Abuse Parity	Section 203, beginning on page 1719. Strengthening parity in mental health and substance use disorder benefits

Vendors that commit to each topic are requested to provide contract language and the claim data file layout for plan sponsor signature.

Wasteful Drugs

Question: Commit to identifying Wasteful drugs defined as having higher prices with no proven incremental clinical value over similar, lower priced drug alternatives. Do you have a program to migrate people from wasteful drugs, where appropriate to the lower cost solution and ensure new subscribers are preauthorized prior to covering wasteful drugs? Commit to provide the exceptions list quarterly and why it was necessary for someone to stay on this identified wasteful drug or if new subscriber why it was approved.

Discounts

Question: Commit to using Medi-Span's classification for brand and generic drugs and use only these classifications when applying discounts and rebates. Commit that brand and generic drug indicators will be in your claims file. Plan sponsor will deal with special circumstances through plan design.

Question: Commit to using the Centers for Medicare and Medicaid Services' specialty drug tier pricing threshold into your criteria for classifying a drug as a specialty drug. Commit you will update the pricing threshold annually to align with CMS. Commit that a specialty drug indicator will be in your claims file.

Question: Commit that you will adjudicate all PBM claims to the lowest net dollar amount.

Rebates

Question: Confirm that claim-level rebates, fees, coupons, and other remuneration from drug manufacturers will be separately reported in the claims file.

Question: Confirm that claim-level rebates, fees, coupons, and other remuneration from drug manufacturers paid to the plan sponsor will be separately reported for CAA compliant reporting requirements.

Prescription Drug Disclosures

Question: Confirm that the necessary data elements including the allowed amount, employer amount plan paid, amount enrollee paid, rebates, average wholesale price, therapeutic drug class, specialty drug indicator, sales tax, and dispensing fees will be in your claims file at an NDC level for CAA compliant reporting requirements.

Prohibition on Gag Clauses

Question: Confirm that claim-level access to provider information, financial information, or any other claim-related financial obligations included in the provider contract will be provided to the plan sponsor. Commit to providing provider information including healthcare provider identification number, name, address, and medical specialty in your claims file.

Question: Commit that you will not restrict the plan sponsor's use of claim data in an RFI or RFP to shop for service providers, accountable care organizations or centers of excellence to improve the cost and quality of our plan for enrollees.

Question: Commit that you will not prohibit co-mingling de-identified, aggregate claims data containing cost and quality information across employers and other carriers for CAA compliant plan administration analysis? Confirm you will not restrict the plan sponsor's use of co-mingled data for benchmarking plan performance, developing a consumer pricing transparency engagement tool, or steering members between provides of the same service type category.

Question: Confirm that there are no sharing restrictions of claim data in your contract that would prevent a plan sponsor from using the data to meet fiduciary obligations.

Question: Commit that claim data can be used to perform certain analytical procedures on claims data, including reverse engineering of pricing and margins for evaluating the reasonableness of service fees.

Question: Commit that in the event of contract termination historical claim data will be retained by the plan sponsor without restrictions.

Compensation Disclosures

Question: Commit that you, your affiliated service providers, and subcontractors confirm to provide a description of services with an itemized list and of all direct and indirect compensation you reasonably expect to receive based on the description of services provided to the covered plan for CAA compliant reporting requirements. Commit that the necessary data elements for tracking will be in your data file.

Question: Commit to communicating, in writing, changes, errors and omissions related to compensation disclosure requirements within the time frames mandated by the CAA.

Mental Health (MH) & Substance Abuse Parity (SA)

Comparative analysis vs. medical and surgical benefits (Med/Surg)

Question: Commit to providing un-restricted, un-redacted MH/SA claim data for CAA compliant comparative analysis to Med/Surg claims.

Question: Commit to not prohibiting co-mingling de-identified, aggregate claims data containing cost and quality information for cross carrier comparisons to determine network adequacy between Med/Surg and MH/SA providers.

Question: Commit to providing a medical management comparative analysis for Med/Surg and MH/SA benefits regarding coverage standards for determining if the treatment is medically necessary, appropriate, experimental, or investigational. Commit to providing a sample report for tracking.

Question: Commit to providing a network admission comparative analysis for Med/Surg and MH/SA benefits regarding coverage standards for determining if the treatment is medically necessary, appropriate, experimental, or investigational. Commit to providing a sample report for tracking.

Question: Commit to providing an analysis comparing factors that influence provider reimbursement rates for delivering Med/Surg and MH/SA healthcare services. Factors may include service type, geographical market, demand for services, provider supply & practice size, training, experience, and licensures. Commit to providing a sample report for tracking.

Question: Commit to providing a prescription drug formulary analysis comparing enrollee access and coverage approvals for drugs used to treat Med/Surg and MH/SA conditions. Commit to providing a sample report for tracking.

Question: Commit to providing a prescription drug management analysis comparing coverage standards such as fail-first or step therapy requirements for drugs used to treat Med/Surg and MH/SA conditions. Commit to providing a sample report for tracking.

Question: Commit to providing other comparative analysis on nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits for CAA compliant analysis. Commit to providing the methods you used to determine parity.

III. Additional materials can be found on Catalyst for Payment Reform's website

i. TPA Data Stewardship Self-Assessment and RFI Questionnaire

ii. 2022 CPR Data Stewardship Addendum to ASO Agreement

iii. Vendor Data Stewardship Self-Assessment and RFI Questionnaire

iv. 2022 CPR Data Stewardship Vendor Contract Language

Access to this site is free for purchasers. To access the materials, you must set up an account with Catalyst for Payment Reform.

IV. Panelists and Additional Resources

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